K113286

APR 27 2012

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	November 5, 2011
Submitter:	GE Healthcare GE Medical Systems Lunar 3030 Ohmeda Drive, Madison WI 53718
Primary Contact Person:	Trishia Dwyer Regulatory Affairs Leader GE Medical Systems Lunar Telephone: (608) 221-1551 ext. 3074 Fax: (608) 646-6488 Email: Trishia.L.Dwyer@ge.com
Secondary Contact Person:	Pernell Abrantes Regulatory Affairs Leader GE Healthcare Telephone: (262) 894-1859 Fax: (414) 647-4410 Email: Pernell.Abrantes@ge.com
Device: Trade Name:	Lunar DPX Series: (DPX-MD+, DPX-MD+ Compact , DPX-NT, DPX-NT Compact, DPX Pro, DPX Bravo, DPX Duo) Lunar Prodigy Series: (Prodigy, Prodigy Compact, Prodigy Pro, Prodigy Pro Compact, Prodigy Primo, Prodigy Primo Compact, Prodigy Advance, Prodigy Advance Compact, Prodigy Forma) Lunar iDXA Series: (iDXA, iDXA Advance, iDXA Pro, iDXA Forma, Lunar iDXA)
Common/Usual Name:	Bone Densitometer
Classification Names:	Bone Densitometer (21CFR 892.1170)
Product Code:	KGI
Predicate Device(s):	Body Composition Software Option for GE Lunar DEXA Bone Densitometers (K071570)
Device Description:	enCORE is the software is used by the series of GE Lunar DXA bone densitometers. Release 14 of the enCORE software (enCORE 14 or enCORE 14.xx) includes some feature enhancements. The software will calculate Resting Metabolic Rate (RMR) and Resting Skeletal Muscle Index (RSMI) using existing scan data. The calculations of RMR and RSMI do not require any changes to the bone densitometer nor does it require additional scanning or radiation exposure beyond the Total Body scans. Additionally, the enCORE software can utilize a MirrorImage function, which estimates Body Composition values

using scanned data from the opposite side of the body if the patient does not fit entirely within the scan window.

The GE Lunar DXA bone densitometers measure the bone mineral density (BMD), lean and fat tissue mass and calculate derivative values of bone mineral content (BMC), area, soft tissue mass, regional soft tissue mass, total soft tissue mass, fat free mass, regional/total soft tissue mass ratio, % fat, region % fat, total body % fat, Android % fat, Gynoid % fat, Android/Gynoid ratio (A/G ratio) and Body Mass Index (BMI).

Intended Use: The enCORE 14 Software Release for the GE Lunar DXA Bone Densitometers is intended for medical purposes to measure bone density, bone mineral content, and fat and lean tissue content by x-ray transmission measurements through the bone and adjacent tissues.

Technology: The enCORE 14 Software Release for GE Lunar DXA Bone Densitometers employs the same fundamental scientific technology as its predicate device.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The Resting Metabolic Rate (RMR) and Relative Skeletal Muscle Index (RSMI) are calculated using scan data collected using the Body Composition software option. There is no change to the scan performed.

The MirrorImage function allows Total Body Composition values to be estimated for patients who are larger than the scan window. The MirrorImage function uses existing scan data. There is no change to the scan performed.

The following quality assurance measures were applied to the development of the product:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

It is concluded that the added features do not impact safety and effectiveness of the enCORE software or the GE Lunar DXA Bone Densitometers in comparison to the predicate device. The enCORE 14 Software Release for the GE Lunar DXA Bone Densitometers with the RMR, RMSI and MirrorImage indications

is substantially equivalent to the predicate device.

Summary of Clinical Tests:

The subject of this premarket submission, the GE Lunar DXA Bone Densitometers, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the enCORE 14 Software Release for the GE Lunar DXA Bone Densitometers with the RMR, RSMI and MirrorImage indications and the added features described herein to be as safe and as effective, and device performance is substantially equivalent to the predicate device, the Body Composition Software Option for GE Lunar DEXA Bone Densitometers.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Trishia Dwyer
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GE Medical Systems Lunar
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MADISON WI 53718

APR 27 2012

Re: K113286
Trade/Device Name: enCORE 14 Software Release for GE Lunar DXA Bone Densitometers
Regulation Number: 21 CFR 892.1170
Regulation Name: Bone densitometer
Regulatory Class: II
Product Code: KGI
Dated: March 12, 2012
Received: March 13, 2012

Dear Ms. Dwyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K_____
Device Name: enCORE 14 Software Release for GE Lunar DXA Bone Densitometers
Indications for Use:

The GE Lunar enCORE software used on the GE Lunar bone densitometer total body scan estimates the Resting Metabolic Rate (RMR) in the male or female population age 18 and older. The data can be displayed in user-defined statistical formats and trends.

The GE Lunar enCORE software used on the GE Lunar bone densitometer total body scan estimates the Relative Skeletal Muscle Index (RSMI) in the male or female population age 18 and older. The data can be displayed in user-defined statistical formats and trends.

The MirrorImage function in the enCORE software used on the GE Lunar DXA bone densitometers can be used to estimate the total body composition and bone mineral density (BMD) when regions of the body are outside of the scan window by using scanned data from the corresponding region(s) on the opposite half of the body.

Prescription Use ___x___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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